

Food and Drug Administration, HHS

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(HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., “motion to quash subpoena”).

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Division of Dockets Management.

(b) *Service.* A party filing a document with the Division of Dockets Management under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party’s last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

§ 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

§ 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent’s liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in §20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

§ 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the

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factors identified in the statute under which the penalty is assessed for purposes of determining the amount of penalty.

(c) Nothing in this section shall be construed to limit the presiding officer or the entity deciding the appeal from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 17.35 Sanctions.

(a) The presiding officer may sanction a person, including any party or counsel for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with a discovery order, including discovery and subpoena provisions of this part, the presiding officer may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(3) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) The presiding officer may exclude from participation in the hearing any legal counsel, party, or witness who refuses to obey an order of the presiding officer. In the case of repeated refusal, the presiding officer may grant judgment to the opposing party.

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

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(f) The presiding officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part.

(g) Sanctions imposed under this section may be the subject of an interlocutory appeal as allowed in § 17.18(b), provided that no such appeal will stay or delay a proceeding.

§ 17.37 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) Direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other parties along with the last known address of the witness. Any prior written statements of witnesses proposed to testify at the hearing shall be exchanged as provided in § 17.25(a).

(c) The presiding officer shall exercise reasonable control over the manner and order of questioning witnesses and presenting evidence so as to:

(1) Make the examination and presentation effective for the ascertainment of the truth;

(2) Avoid undue consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The presiding officer shall permit the parties to conduct such cross-examination as may be required for a full disclosure of the facts.

(e) At the discretion of the presiding officer, a witness may be cross-examined on relevant matters without regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, a witness may be cross-examined on relevant matters with regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.